Approved by the regional ethical committee in Östergötland, Sweden. *May 2014*

SAP for the NEXit 3.0 study

1. Background

The main NEXit 3.0 study is a 2 arm RCT with an intervention group and a delayed intervention control group. The intervention is supposed to make student to make a quit attempt and hopefully totally stop smoking.

The participants are students from colleges and universities all over Sweden with an anticipated numbers of invited participants around 3-400.00 students. Both daily smokers and occasional smokers are invited to participate. Grade of motivation, or lack of motivation to stop smoking, was no criteria to participate. So the study could be called a *smoking cessation induction study* according to the literature.

The intervention consist of a 1-4 weeks of motivational messages before setting a stopdate and then a 12 weeks intervention. This means that the total intervention time could be from 13 to 16 weeks. Considering the time the participants have from getting the first invitation to participate (3 weeks) before finally deciding to enter the study we have set the time of the follow- up to 19 weeks from the first invitation.

The aim of the study is to evaluate the effect of the sms support in comparison to a delayed intervention control group. The primary hypothesis is that the "quit rate" (Represented by 8 weeks "prolonged abstinence" and 4 weeks "point prevalence smoking abstinence")in the intervention group twice as high as in the control group (i.e. 10 % versus 5 5). Secondary hypothesis is that the 7-days point prevalence smoking abstinence, number of quit attempts and the use of other smoking cessation services is twice as high in the intervention group compared to the control group.

A sub study nested within the main study will be performed in order to explore to what extend it is possible to add reminders or change the mode of delivery in order to get a higher response rate in the follow-up. This could be an interesting study since low response rate is something that is common and hinders a good data quality. The methodology has not yet been decided for this sub study but will include various attempts to get non responders to the first series of invitation (by mail) to answer the follow-up questionnaire . This could f.e.x include more (frequent) reminders or reminders via sms.

2. Variables to be included in the analysis of the main study

a) Sign up questions

1. What is your age? 2. Are you man/woman? 3. Are you single/married/co-habitant/having children at home?
4. How many years have you been smoking?
5. State the average numbers of cigarettes who smoke
   a) If daily smokers: xx cigarettes b) If non daily smoker: xx cigarettes per month
6. How long time after waking up do you have your first cigarette?
   - Less than 6 minutes (3p)
   - Between 6-30 minutes (2p)
   - Between 31 and 60 minutes (1p)
   - More than 60 minutes (0p)
   - Not applicable since I am not a daily smoker
7. How many cigarettes do you smoke daily
   - Less than 11 cigarettes (0p)
   - Between 11 and 20 cigarettes (1p)
   - Between 21-30 cigarettes (2p)
   - More than 30 cigarettes (3p)
   - I am not a daily smoker. (0p)
8. Do you have difficulties refraining from smoking where it is not allowed?
   - Yes (1p)

No (0p)

9. What cigarettes do you have most difficulties refraining from?
   The first one in the morning (1p)
   Someone else (0p)
10. Do you smoke more in the morning than the rest of the day
   Yes (1p)
   No (0p)
11. Do you smoke even if you are sick and have to stay in bed
   Yes (1p)
   No (0p)
12. How do you think about quitting smoking
   I have not thought about quitting smoking
   I have thought about quitting smoking, but not right now
   I think about quitting smoking
   I have decided to quit smoking
   I have started preparation for quitting smoking

13. How important is it for you to stop smoking?
   Scale 1-10 where 1 stands for not important at all and 10 very important
14. Have you ever tried stop smoking?
   If yes: How many times?
   No
15. Have you ever used any kind of nicotine replacements?
   If yes: how many times/periods?
   No
16. Have you ever been prescribed special drugs as a help for quitting smoking (i.e Champix or Zyban)Yes
   No

17. Have you ever receiving professional counselling on an individual basis or in a group
   Yes
   No
18. Have you ever called the national telephone quit smoking help-line

   Yes
   No

Question numbers 6-11 gives an index with 0-10 points (*For points see the response options)* (Fagerström dependence scale). 0-3 No dependence, 4-5 p low dependence, 6-10 – strong dependence.

b) Follow-up questions at 15 weeks

1. Have you been smoking more than 5 cigarettes the last 8 weeks
   Yes
   No
2. Have you been smoking any cigarettes the last 4 weeks
   Yes (Go to question 3)
   No (go to question 6)
3. Have you been smoking any cigarettes the last 7 days
   Yes (go to question 4)
   No (Go to question 6)
4. Are you a daily smoker
   Yes: How many cigarettes do you smoke daily:__
   No: State how many cigarettes you have been smoking <u>during</u> the last 4 weeks:__

5. How long time after waking up do you have your first cigarette?
   Less than 6 minutes
   Between 6-30 minutes
   Between 31 and 60 minutes
   More than 60 minutes
   Not applicable since I am not a daily

6. How many quit attempts have you had since you received the first invitation to the study 15 weeks ago: __

7. Have you sought and received any other support for quitting smoking since you received the first invitation to the

study 15 weeks ago (*Multiple response options)*

Yes, I have called the national quit line
Yes, I have used nicotine replacement products
Yes, I have received professional counselling in a group
Yes, I have received professional counselling on an individual basis
Yes, I have been ordered prescribed medicine for helping quit smoking by my physician
Yes, I have received other forms of support. Please write what kind of support.
No, additional support

c. Other variables collected

Numbers invited
Numbers answering not smoking – date for each person
Numbers answering smoking but do not want to participate– date for each person
Numbers of smokers consenting to get more information about the study– date for each person
Numbers of smokers consenting to participating– date for each person
Numbers of smokers answering the baseline survey
Numbers of smokers confirming their telephone number
Numbers of smokers setting a stop date – dates for quiting smoking
Randomisation group
Numbers of participants stopping the intervention *(If a participant actively stops the intervention during the 8 weeks period.)* – dates for each person
Date for restarting the intervention (if applicable). Dates for each person
Numbers and types of extra messages requested
Time to answering the follow up assessment - dates for each person and mode of delivery (Mail, sms or telephone)

3. Outcome measures in the main study.

Primary outcome measure:

1. Self-reported "prolonged abstinence", not having smoked more than 5 cigarettes the last 8 weeks .

2. Self-reported 4 weeks point prevalence of smoking abstinence (not having smoked a single cigarette).

Secondary outcome measures:

3. Self-reported 7-days point prevalence smoking abstinence (defined as not smoking any cigarettes in the past 7 days) .

4. Number of quit attempts during since the first invitation to the study (15 weeks)

5. Use of other smoking cessation services (medication, counselling, calling help line etc.) since first invitation to the study (15 weeks).

Possible variable for effect modification:

Age, gender, motivation to quit, Fagerström Nicotine Dependence scale (3 levels), numbers of years smoking, average numbers of cigarettes smoking at baseline, use of professional help or nicotine replacement/medication previously, number s of previous quit attempts. Also time to respond to the invitation and time to decide a quit date.

Extra data to be reported:

6. Among students still smoking: Change in average the number of cigarettes per day in the last 4 weeks.

7. Among students still smoking: Change in time after waking up to the first cigarette.

8. User satisfaction with the intervention (A number of variables).

4. Descriptive analysis of the main study

The flow of study participants will be displayed in a flowchart (ref: Nexit 3.0 protocol). The number of screened students who fulfilled the study inclusion criteria, and the number included in the primary and secondary analyses as well the reason for exclusion from these analyses will be reported.

Summary tables (descriptive statistics and/or frequency tables) will be provided for baseline and follow-up variables, as appropriate. Continuous variables will be summarized with descriptive statistics (n, mean, standard deviation for data with normal distribution, or median and interquartile range for non-normally distributed data). Frequency counts and percentages of subjects within each category will be provided for categorical data.

Among tentative tables will be: Summary table over numbers of participants setting a stop date and starting the intervention; numbers stopping the intervention (mean time staying with the intervention), numbers of participants requesting extra messages (three categories) and number of extra messages requested.

5. Statistical analysis of the main study

Primary analyses

Demographic data and baseline characteristics will be compared between the intervention and control groups to assess the degree to which comparability of randomisation was achieved.

Follow-up variables will be summarized for each group and compared between randomised groups. Significance tests will be performed by Pearson χ^2 test for qualitative variables and for continuous variables by Student's t-test for normally distributed data, or by Wilcoxon-Mann-Whitney group for non-normally distributed data.

The binary outcomes of self-reported prolonged abstinence for 8 weeks, 4-weeks prevalence of smoking abstinence, self-reported 7-day point prevalence smoking abstinence, and use of other smoking cessation services will be analysed by logistic regression and results presented as odds ratios with 95% CI.

Number of quit attempts will be analysed by linear regression or mathematically transformed prior to fitting the regression depending of its distribution.

Other / sensitivity analyses

Baseline variables will be compared between those who do/do not respond at follow-up.

Effect modification analysis will be performed for the comparison made in all outcome tables in relation to following potential effect modifiers: age, gender, motivation to quit, Fagerström Nicotine Dependence scale (3 levels), numbers of years smoking, average numbers of cigarettes smoking at baseline, use of professional help or nicotine replacement/medication previously, number of previous quit attempts, time to respond to the invitation and time to decide a quit date. Each effect modification will be assessed by adding the appropriate interaction term to the adjusted regression model.

There are two primary and three secondary outcomes. Consideration for adjustment for multiplicity of comparisons will be discussed.

All tests will be performed two-sided with a 5% level of significance.